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Box Interference

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The opinion in support of the decision being entered today is <u>not</u> binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

MINORU TSURUTA, SHIRO BITO, SHUICHI KIMURA, AKITO MUKAIZAWA, SEIJI KURAMOTO, TSUYOSHI TSUKAGOSHI, AKIO NAKATA, AKIHIRO TAGUCHI, KAZUHIKO OOZEKI, HITOSHI MIZUNO, SHUICHI TAKAYAMA, YOSHINAO OAKI, KEISUKE SAITO and TOSHIHIKO SUZUTA,

Junior Party,

v.

PAUL C. NARDELLA,

Senior Party.

Patent Interference No. 103,950

Before: McKELVEY, <u>Senior Administrative Patent Judge</u>, and CRAWFORD and MEDLEY, <u>Administrative Patent Judges</u>.

CRAWFORD, Administrative Patent Judge.

MEMORANDUM OPINION AND JUDGMENT

1. The above-referenced interference was declared on July 18, 1997 (Paper No. 1, page 1) with two Counts.

2. Count 1 reads as follows:

A surgical device for stapling and fastening body tissue, comprising:

an operation section operated outside a body cavity;

an insertion section extending from said operation section for insertion into a body cavity;

electrosurgical energy applying means provided within said insertion section, for applying electrosurgical energy to body tissues within a body cavity;

a cartridge provided within the insertion section, said cartridge containing a plurality of staples, the staples each having at least two legs which are to be inserted into the body tissues;

staple-applying means provided within the insertion section, and coupled to said cartridge for applying at least one staple from said cartridge to target tissue through said insertion section;

staple-deforming means provided within the insertion section for deforming the at least one staple applied to the target tissues by said staple-applying means, thereby stapling the target tissues together; and

current-supplying means, extending through said insertion section from said operation section to said electrosurgical energy applying means to prevent bleeding of treated target

tissues, said electrosurgical energy applying means being electrically connected to the at least one staple applied to the target tissues and applying electrosurgical energy to the at least one staple; said cartridge, said staple-applying means and said staple-deforming means all being operable by operating said operation section.

Count 2 reads as follows:

A surgical device for stapling and fastening body tissue, comprising:

an operation section operated outside a body cavity;

an insertion section extending from said operation section for insertion into a body cavity;

electrosurgical energy applying means provided within said insertion section, for applying electrosurgical energy to body tissues within a body cavity;

a cartridge provided within the insertion section,
said cartridge containing a plurality of staples, the
staples each
having at
least two legs
which are to
be inserted
into the body

tissues;

staple-applying means provided within the insertion section, and coupled to said cartridge for applying at least one staple from said cartridge to target tissue through said insertion section;

staple-deforming means provided within the insertion section for deforming the at least one staple applied to the target tissues by said staple-applying means, thereby stapling the target tissues together; and

current-supplying means, extending through said insertion section from said operation section to said electrosurgical energy applying means to prevent bleeding of treated target tissues, said electrosurgical energy applying means being electrically connected to the at least one staple applied to the target tissues and applying electrosurgical energy to the at least one staple;

said cartridge, said staple-applying means and said staple-deforming means all being operable by operating said operation section; and

a cutter for cutting the target tissues, said cutter being provided within the insertion section, said

cutter comprising an electrically conductive cutter and said electrosurgica 1 energy applying means including means for applying electrosurgica l energy to said cutter to prevent bleeding due to cutting of the target tissues, and wherein:

said staple-deforming means and said cartridge are located near said electrosurgical energy applying means in order to staple the target tissues to be cut by said cutter.

The senior party Nardella's claims 35, 36, 38, 39 and 40-42 and junior party Tsuruta's claims 1 and 2 were designated as corresponding to Count 1. Nardella's claims 37 and Tsuruta's claim 3 were designated as corresponding to Count 2.

The following motions have been filed:

Nardella's Preliminary Motion No. 1 (Paper No. 15)

pursuant to 37 CFR § 1.633(c)(3) to designate claims 4 and 10

through 16 of Tsuruta's involved U.S. Patent No. 5,389,098

("Tsuruta patent") as corresponding to Count 1 and claims 5

through 9 as corresponding to Count 2. Opposition (Paper No. 23). Reply (Paper No. 35).

Tsuruta's Preliminary Motion No. 4 (Paper No. 39)

pursuant to 37 CFR §§ 1.635 and 1.645(b) to seek consideration

of belatedly filed preliminary motions. Opposition (Paper No.

42). Reply (Paper No. 46).

Tsuruta's Preliminary Motion No. 5 (Paper No. 40)

pursuant to 37 CFR §§ 1.635 and 1.662(c) to delete certain

claims of Nardella's application from being involved in the

present interference. Opposition (Paper No. 43). Reply (Paper No. 47).

Tsuruta's Preliminary Motion No. 6 (Paper No. 41)

pursuant to 37 CFR § 1.633(a) for judgment that certain claims

of Nardella's involved application are not patentable.

Opposition (Paper No. 44). Reply (Paper No. 48).

We note at the outset, that a party filing a motion in an interference, including a preliminary motion, has the burden of proof to show that it is entitled to the relief sought in the motion. 37 CFR § 1.637(a).

Nardella's Preliminary Motion No. 1

Nardella Preliminary Motion No. 1, seeks an order designating (1) claims 4 and 10 through 16 of Tsuruta's patent as corresponding to Count 1 and (2) claims 5 through 9 of Tsuruta's patent as corresponding to Count 2.

In order to prevail on this motion, Nardella must establish by a preponderance of the evidence that claims 4 through 16 recite the "same patentable invention" as a claim involved in the interference whose designation as corresponding to Count 1 or Count 2 Nardella does not dispute.

37 CFR § 1.637(c)(3)(ii).

Pursuant to 37 CFR § 1.601(n):

Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

We note at the outset that Nardella has not attempted to prove that the subject matter recited in claims 4 through 16 is the same patentable invention as the invention of an involved claim whose designation as corresponding to the Count 1 or Count 2 Nardella does not dispute as required by 37 CFR § 1.637(c)(3)(iii). Rather, Nardella has attempted to prove that the subject matter recited in claims 4 through 16 is the same patentable invention as Count 1 or Count 2 or of another claim not designated as corresponding to either Count 1 or Count 2. However, in order to advance the resolution of this interference, we will decide this motion as if Nardella had properly compared the recitations of Tsuruta's claims 4 through 16 to Nardella's claim 35 which is similar to Count 1 and to Nardella's claim 37 which is similar to Count 2.1

The major differences between Nardella's claim 35 and Count 1 and Nardella's claim 37 and Count 2 is that Nardella's claims 35 and 37 recite a high frequency means and Counts 1 and 2 recite an electrosurgical means and claims 35 and 37 recite that various elements are provided at the distal end of the insertion section and Counts 1 and 2 recite that these

Nardella's preliminary Motion 1 is directed to the obviousness of the subject matter of claims 4 through 16. As such, Nardella has the burden of establishing that the teachings of the prior art (assuming that Nardella's claims 35 or 37 are prior art) would have suggested the subject matter of claims 4 through 16 to a person of ordinary skill in the art. See In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993).

In regard to Tsuruta's claim 4, Nardella has discussed only the first and second deforming means of claim 4.

Nardella has not shown that all the elements of claim 4 would have been obvious in view of Nardella's claim 35. Notably, Nardella has not shown that a "drive means for selectively driving said first and second deforming means," would have been obvious to a person of ordinary skill in the art. In fact, Nardella's motion does not mention the drive means.

features are disposed in the insertion section.

² This is a problem we find throughout Nardella's preliminary Motion No. 1. Nardella has discussed some of the differences between the claim recitations and Nardella's claims 35 or 37 but not all of the differences. However, Nardella is under a burden to address each element of claims 4 through 16 of the Tsuruta patent in order to establish that these claims would have been obvious to a person of ordinary skill in the art.

(We note that a declaration executed by Mr. Williamson which was filed by Tsuruta, indicates
that he regards the provision of selectively drivable staple
deforming means as recited in claim 4 to be a significant
departure from the prior art.)

Our appellate reviewing court, in **Smith Industries** Medical Systems, Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1356, 51 USPQ2d 1415, 1420 (Fed. Cir. 1999), has noted that there is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time of the invention. relevant inquiry is whether there is a reason, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the teachings of the references, and that would also suggest a reasonable likelihood of success. Such a suggestion or motivation may come from the references themselves, from knowledge by those skilled in the art that certain references are of special interest in a field, or even from the nature of the problem to be solved. Nardella has not identified the source of the various claim limitations in the prior art, much less a motivation, teaching or suggestion to combine them. See also In re Kotzab, 217

F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000) (identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention; rather, to establish obviousness based on a combination of elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant).

Accordingly, we conclude that Nardella has failed to meet its burden of establishing obviousness with regard to claim 4.

In regard to Tsuruta's claim 5, Nardella argues that the rotatably connected anvil and cartridge and the curved distal portion of the anvil and cartridge as recited in Tsuruta's claim 5 are disclosed in Published Examined Japanese Utility Model Application No. 38-19282 and Published Examined Japanese Utility Model Application No. 60-41924. Nardella also argues that U.S. Patent No. 5,156,315 (Green '315) to Green discloses a straight proximal portion which curves in the distal region of the stapling section as recited in Nardella's claim 37.

Nardella does not discuss why the modification of the anvil and cartridge in the prior art (Nardella's claim 37) would have been suggested by the prior art.³

Nardella further states that staples having both jaws rotatable at the distal end of the anvil and cartridge with curved distal portions were well known in the art as illustrated by U. S. Patent No. 5,040,715 to Green (Green '715); Published Examined Japanese Utility Model Application No. 60-41924; U.S. Patent No. 3,079,606 to Bobrov; and U.S. Patent No. 3,490,675 to Green.

However, Nardella has not discussed why a person of ordinary skill in the art would have been motivated to modify the stapler of the prior art (Nardella's claims 35 and 37) so that the anvil and cartridge are rotatably connected or so that the anvil and cartridge are curved.

Tsuruta argues that the recitation in claim 5 that the high-frequency signal which is applied to the staples is also

³ Throughout the motion, Nardella directs our attention to various prior art references which, according to Nardella, disclose a feature or features recited in claims 4 through 16 which is not recited in Nardella's claims 35 or 37 but fails to discuss how the modification of the invention of Nardella's claims 35 or 37 so as to include the feature would have been obvious to a person skilled in the art.

applied to the cutter patentably distinguishes claim 5.

However, Nardella's claim 37 recites that the high frequency energy is applied to the staple and the cutter. As such, Nardella is correct in arguing that Tsuruta has made no meaningful argument to the motion in respect to claim 5.

Moreover, the fact that Tsuruta has not meaningfully opposed the designation of claim 5 as corresponding to Count 2 does not relieve Nardella of the burden imposed by 37 CFR § 1.637.

In view of Nardella's lack of discussion concerning the suggestion or motivation to modify the surgical device of the prior art (Nardella's claim 37) such that the anvil and cartridge are curved and rotatably connected, it is our holding that Nardella has failed to meet its burden of establishing obviousness with regard to claim 5.

In regard to claim 6, Nardella argues that having a cutting guide which curves along the lengths of the anvil and cartridge and includes a drives means for moving the cutter along the cutter guide are inherent features in the prior art (Nardella's claim 37) and is clearly shown in Green '315.

 $^{^{4}}$ Count 2 recites that the electrosurgical energy is applied to the staple and the cutter.

However, Nardella has not submitted any credible evidence that establishes this feature to be an inherent feature of the prior art (Nardella's claim 37). We note that argument of counsel is no substitute for evidence. Meitzner v. Mindick, 549 F.2d 775, 782, 193 USPQ 17, 22 (CCPA 1977) cert. denied 434 U.S. 854, 195 USPO 465 (1877). In addition, Nardella has not explained why a person of ordinary skill in the art would have been motivated to modify the stapler of the prior art (Nardella's claim 37) so as to have a cutting guide which curves along the lengths of the anvil and cartridge and includes a drive means for moving the cutter along the cutter quide. As such, Nardella has not established the obviousness of the subject matter of claim 6. In regard to claim 7, Nardella, directs our attention to the recitations in claim 7 of (1) a plurality of holes formed on both sides of the cutter guide and (2) a staple forming means comprising a plurality of grooves. Nardella argues that these features are obvious embodiments of the cutting and stapling device of the prior art (Nardella's claim 37). Nardella argues that virtually every surgical cutting and stapling device that uses a parallel cartridge and anvil, including Green '315, for example, has these features.

However, Nardella does not discuss why it would have been obvious to a person of ordinary skill in the art to include these features in the surgical device of the prior art (Nardella's claim 37). The conclusory statement that these features are obvious modifications is insufficient to meet Nardella's burden of establishing obviousness with respect to claim 7.

With respect to claim 8, Nardella argues that the recitations in claim 8 of a operation section which comprises a connecting section, an operating section for opening and closing the anvil, and cartridge and drive section for driving the cutter are inherent features in the prior art device (Nardella's claim 37) and that these features are disclosed in Green '715. Nardella has not directed us to evidence that would establish that these features are inherent. While Nardella directs our attention to Green '715, Nardella has not established why a person of ordinary skill in the art would be motivated to include the features of Green '715 in the surgical device defined by Nardella's claim 37.

In regard to claim 9, Nardella argues that the recitations in claim 9 of a drive means and staple applying means each including flexible portions which are bendable

along the cutter guide are inherent in the prior art

(Nardella's claim 37). However, Nardella has failed to direct
us to evidence to prove this assertion. Nardella has not
established the obviousness of the subject matter of claim 9.

In regard to claim 10, Nardella states that it was well known in the art to provide staple applying means complete with staple pushers and staple forming means in an end face. Nardella states that U.S. Patent No. 4,747,531 to Brinkerhoff and U.S. Patent No. 4,671,279 to Hill disclose such end staplers and their workings. While recognizing that claim 10 also recites that the applying means touches the target tissue, Nardella dismisses this feature without comment.

Tsuruta argues that there are many differences between claim 10 and Nardella's claim 35 which were not discussed by Nardella. We agree with Tsuruta that Nardella has a duty to discuss all the differences between Nardella's claim 35 and Tsuruta's claim 10.

In addition, we agree with Tsuruta that Nardella has failed to provide analysis of why the subject matter of claim 10 would have been obvious to a person skilled in the art in view of the teachings of the prior art. While Nardella argues in the reply that the application of electrosurgical elements

of Nardella's claim 35 to another known surgical stapler embodiment renders the subject matter of claim 10 obvious over the subject matter of Nardella's claim 35, this is not an argument which establishes why one of ordinary skill in the art would have been motivated by the teachings or suggestions of the prior art to apply the electrosurgical energy through the projecting member. As such, Nardella has not established the obviousness of the subject matter of claim 10.

In regard to claim 11, Nardella argues that it is well known that the rigid distal and proximal ends of the stapler may be adapted to permit rotation of the staple forming assembly relative to the handles and directs our attention to U.S. Patent No. 3,643,851 to Green and U.S. Patent No. Re. 28,932 to Noiles. However, Nardella has not established why a person of ordinary skill in the art would have been motivated to modify the stapler of Nardella's claim 35 so that the rigid distal and proximal ends of the stapler are rotatably coupled. As such, Nardella as failed to meet its burden of establishing obviousness with regard to claim 11.

In regard to claim 12, Nardella states only that claim 12 depends from claim 10 and is not patentably distinct from the prior art (Nardella's claim 35). Nardella has not met its

burden of establishing obviousness of claim 12 for the reasons stated above for claim 10.

Nardella argues that claims 13 and 15 recite no features that are not also recited in claims 10 and 12. Nardella does not supply the suggestion for modification of the prior art which we found missing in Nardella's argument above for claim 10. Therefore, Nardella has not met its burden of establishing obviousness with respect to claims 13 and 15.

In regard to claim 16, Nardella argues that the Vittenburger article discloses a cutting, cauterizing and stapling device for stomach resection and bowel anastomosis that includes the provision of a tying means. Nardella concludes that the subject matter of claim 16 is obvious over the prior art (Nardella's claim 35). Nardella has not met its burden of establishing obviousness with respect to claim 16 because Nardella has not established why a person of ordinary skill in the art would have been motivated to modify the device of the prior art (Nardella's claim 35) so as to include a tying means.

Nardella has not specifically argued the provisions of claim 14 and as such has failed to establish obviousness with respect to claim 14.

As Nardella has not established that a person of ordinary skill in the art would have been motivated to modify the prior art (Nardella's claims 35 or 37) so as to include the features recited in Tsuruta's claim 4 through 16, Nardella preliminary motion is denied.

Tsuruta's Preliminary Motion No. 4

Tsuruta has filed a preliminary motion under 37 CFR §§

1.635 and 1.645(b) to seek consideration of belatedly filed

preliminary Motion Nos. 5 and 6. Tsuruta argues that the

filing of a disclaimer by Nardella in U.S. Patent No.

5,665,085 created new issues and necessitated the filing of

Tsuruta's preliminary Motion Nos. 5 and 6. We agree that

inasmuch as Tsuruta was not notified about the filing of the

disclaimer until May 4, 1998, Tsuruta could not have filed

preliminary Motions Nos. 5 and 6 prior to the due date (March

5, 1998) of the preliminary motions. Therefore, Tsuruta has

established good cause why preliminary Motions Nos. 5 and 6

were not filed by March 5, 1998.

In view of the foregoing, Tsuruta's motion No. 4 is granted.

Tsuruta's Preliminary Motion No. 5

Tsuruta moves to designate Nardella's claims 38 through 42 of the Nardella's involved application ("Nardella application"), as not corresponding to a count. Tsuruta argues that claims 38 through 42 of Nardella's application Serial No. 08/477,289 are identical to claims 1 through 3, 5 and 9 of Nardella's U.S. Patent No. 5,665,085 ("Nardella patent") and that there are only minor differences between claim 42 of Nardella's application and claim 9 of Nardella's application. Tsuruta argues that the filing of the statutory disclaimer does not obviate the statutory double patenting problem created by these two sets of claims.

Applicable law⁵

i.

Tsuruta alleges that Nardella's involved claims 38

through 42 are unpatentable based on what appears to be

"statutory" double patenting (as opposed to "obviousness-type"

double

 $^{^{\}scriptscriptstyle 5}$ $\,$ This portion of the opinion was authored by Senior Administrative Patent Judge McKelvey.

patenting). Tsuruta bases its double patenting position on claims 1-3, 5 and 9 of Nardella's U.S. Patent 5,665,085, issued 9 September 1997, containing claims 1-29. On 30 April 1998, Nardella's assignee (Medical Scientific, Inc.) disclaimed claims 1-3, 5 and 9 of the patent. 35 U.S.C. § 253. Likewise, Nardella's involved application contains a "terminal disclaimer" which provides that any patent issued on the application will expire on the date Nardella's '085 patent would have expired had a disclaimer not been filed.

Our review of arguably relevant precedent of our appellate reviewing court leaves us with some doubt as to whether that precedent is applicable, and if so, whether it is conflicting. Accordingly, we undertake a respectful analysis of the case law with the view to sorting out what law we think we should apply in this case recognizing that there is a possibility that our appellate reviewing court reasonably could reach a different conclusion. Also relevant is a provision in the Manual of Patent Examining Procedure (MPEP). For the reasons hereinafter given, we have determined that the appellate court precedent is not controlling and that a provision of the MPEP should be adopted as the law to be applied in this case.

ii.

(1)

We start with <u>In re Heinle</u>, 342 F.2d 1001, 145 USPQ 131 (CCPA 1965). <u>Heinle</u> involved a double patenting rejection.

In a continuation application—the application on appeal—Heinle claimed what the CCPA refers to an element E. Heinle's parent application had issued as a patent and claimed the combination of A, B, C, D and E. Heinle argued the double patenting rejection was improper because

- (1) the element E was patentable over the combination A, B, C, D and E and
- (2) the filing of (a) a disclaimer of the patent and (b) a terminal disclaimer in the application to cause any patent on the application to expire when the disclaimed patent otherwise would have expired.

A CCPA 3-2 majority agreed with Heinle that the element E was patentable over the combination of A, B, C, D and E.

Accordingly, it reversed the double patenting rejection on its merits.

(2)

Notwithstanding its reversal on the merits, the CCPA majority undertook a discussion of the effect of the

disclaimers. In particular the CCPA majority notes, 342 F.2d at 1007, 145 USPQ at 136:

It should be clear that we do not find it necessary to rely on the disclaimers, or either of them, to reverse in this case. We nevertheless hold the disclaimers to be effective in removing two of the frequently cited reasons given in support of double patenting rejections, extension of monopoly in point of time and prevention of the issuance of two patents on one invention. With the disclaimers of record, we can find no possible support for the double patenting rejections in this case.

The CCPA majority's above-quoted paragraph appears to set out inconsistent positions. First, the CCPA majority states "[i]t should be clear that we do not find it necessary to rely on the disclaimers, or either of them, to reverse in this The position is absolutely correct in view of the CCPA's disposition of the double patenting rejection on its Hence, it would not be unreasonable to say that what the CCPA majority says about the disclaimers is dictum.6 Second, however, the CCPA majority states "[w]e nevertheless hold [that] *** [w]ith the disclaimers of record, we can find no possible support for the double patenting rejections in this case" (bold added). Hence, what started out as dictum can be argued to have become an alternative holding in the case which would fully support the CCPA's decision. Stated in other terms, had the CCPA majority bottomed its decision on the disclaimers, it would not have had to reach the merits.

For a discussion of what constitutes $\underline{\text{dictum}}$, $\underline{\text{see}}$ $\underline{\text{United States v. Crawley}}$, 837 F.2d 291 (7th Cir. 1988).

Nevertheless, the CCPA majority explicitly stated that "we do not find it necessary to rely on the disclaimers ***."

(3)

Our Supreme Court has observed that where a court rests its judgment on two separate ground, both grounds are of equal validity and neither is <u>dictum</u>. <u>Woods v. Interstate Realty</u>

Co., 337 U.S. 535, 537 (1949); <u>United States v. Title</u>

<u>Insurance & Trust Co.</u>, 265 U.S. 472, 486 (1924). Hence, the real question becomes whether the <u>Heinle</u> disclaimer holding was intended to be a separate ground upon which the CCPA made its decision.

This is not the first time this board has found it necessary to consider whether a CCPA holding was dictum. See Ex parte McGrew, 41 USPQ2d 2004, 2006 n.5 (Bd. Pat. App. & Int. 1995), aff'd sub. nom In re McGrew, 120 F.3d 1236, 43 USPQ2d 1632 (Fed. Cir. 1997), where we found it necessary to resolve a question of whether the CCPA's opinion in In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980), contained dictum. We held that a statement in the Sasse opinion that claims could not be rejected under 35 U.S.C. § 135(b) was not necessary to the Sasse decision. 41 USPQ2d at 2006 n.5. On appeal, the Federal Circuit agreed and explicitly held that

the <u>Sasse</u> statement was <u>dictum</u> and therefore not binding precedent. 120 F.3d at 1238-39, 43 USPQ2d at 1635.

Unlike the unanimous opinion in <u>In re Sasse</u>, two judges concurred in <u>In re Heinle</u>, 342 F.2d at 1008, 145 USPQ at 136-37. Judge Almond, joined by Judge Martin, states "I cannot agree with the majority that it is unnecessary to rely upon the disclaimers in order to reverse the board." The concurring judges felt that the claimed element "is obvious" and therefore the terminal disclaimer was necessary to prevent "an unlawful extension of the monopoly." All concerned can recognize the truism that a concurring opinion can be characterized as a want-to-be majority opinion and that a court's majority opinion, not a concurring opinion, is what counts. The fact that

- (1) two of the five CCPA judges participating in Heinle found it necessary to rely on the disclaimers to reverse,
- (2) that the majority does not explicitly state in its opinion that the concurring judges have it wrong and
- (3) all five judges seem to say that the majority did not find it necessary to rely on the disclaimers,

suggests to us, while not totally free from doubt, that the CCPA majority's discussion about the disclaimers is <u>dictum</u>.

iii.

(1)

Recently, the Federal Circuit entered a merits panel decision in <u>Eli Lilly & Co. v. Barr Laboratories</u>, <u>Inc.</u>, 251 F.3d 955, 58 USPQ2d 1865 (Fed. Cir. May 30, 2001).

In <u>Eli Lilly</u>, the Federal Circuit had before it a double patenting issue. On the "merits," the Federal Circuit held that claim 7 of the "patent on appeal" (U.S. Patent 4,626,549, issued 2 December 1986) was invalid on double patenting grounds over claim 1 of a "second patent" of Eli Lilly (U.S. Patent 4,590,213 issued 20 May 1986). The patent on appeal was due to expire at the end of its statutory term, but on 7 July 1998, a statutory disclaimer was filed in connection with the second patent. Accordingly, the life of the second patent ended on 7 July 1998.

 $^{^7}$ We were unable to find the date of the disclaimer in the Federal Circuit's <u>Eli Lilly</u> opinion. However, we take official notice based on the USPTO's PALM system that the disclaimer was accepted by the USPTO on 7 July 1998, during pendency of the <u>Eli Lilly</u> litigation.

In note 5 of its opinion, the Federal Circuit states in a rather straightforward manner that "[a] patent owner cannot avoid double patenting by disclaiming the earlier patent."

The entire note reads:

A patent owner cannot avoid double patenting by disclaiming the earlier patent. Further, because Lilly disclaimed the '213 patent [, i.e., the "second patent"], it cannot now terminally disclaim the '549 patent [, i.e., the "patent on appeal",] to expire at the time the '213 patent would have expired had it not been disclaimed. That is, the fact that the '213 patent has been disclaimed is of no help to Lilly, as double patenting precludes claim 7 of the '549 patent from extending beyond the termination date of the '213 patent, whether that termination date is at the end of its normal term or, as in this case, is the date it is terminated via disclaimer.

In our opinion, the discussion in note 5 of <u>Eli Lilly</u> can be argued to be inconsistent with the disclaimer <u>dictum</u> in Heinle.

(2)

The discussion in note 5 of <u>Eli Lilly</u> also would appear to be <u>dictum</u> given that Eli Lilly had not filed a terminal disclaimer with respect to the patent on appeal. However, we can understand why the <u>Eli Lilly</u> court made the observation in its note 5. Had Eli Lilly terminally disclaimed that portion term of the patent on appeal after 7 July 1998, a case or

controversy still might have existed—had the patent on appeal not otherwise have been held invalid—as to acts of infringement taking place prior to 7 July 1998. Barr's ANDA application, filed with the FDA sometime in 1995, could have been determined to have been an act of infringement under 35 U.S.C. § 271(e)(2)(A). The statute of limitations for alleged infringement of a patent is six years. 35 U.S.C. § 286. Hence, Eli Lilly could allege that an act of infringement occurred before 7 July 1998. Whether any practical relief could be granted under 35 U.S.C. § 271(e)(4) is a matter we need not address.

iv.

Manual of Patent Examining Procedure, § 804.02 (7th ed.,
Rev. 1, Feb. 2000), makes the following observation (bold
added):

A rejection based on the **statutory type** of double patenting can be avoided by canceling the conflicting claims in all but one of the pending application(s) or patent, or by amending the conflicting claims so that they are not coextensive in scope. A terminal disclaimer is not effective in overcoming a statutory double patenting rejection.

The MPEP does not state the underlying rationale in support of, or any other justification for, the policy set out

in § 804.02. Likewise, we note that the policy does not seem to embrace "obviousness-type" double patenting. The rejection reversed in <u>Heinle</u> was not a statutory double patenting rejection. Hence, it does not appear that the policy set out in the MPEP is squarely based on the decision in Heinle, whether the disclaimer discussion by Heinle majority is characterized as a holding or dictum. We note, however, that the MPEP is entirely consistent with the majority's discussion of disclaimers in Heinle, whether that discussion be considered a holding or dictum. The double patenting issue involved in Eli Lilly does not appear to have involved statutory double patenting because the subject matter of claim 7 of the patent on appeal seems to have been an embodiment within the scope of the claims of the second patent. In re <u>Vogel</u>, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970) (a good test, and probably the only objective test, for "same invention," is whether one of the claims could be literally infringed without literally infringing the other; if it could be, the claims do not define identically the same invention).

v.

In this case, claims 38 through 42 of Nardella's application are the same as claims 1-3 and 5 of Nardella's disclaimed patent. Claim 42 of the Nardella application differs in minor respects from Nardella patent claim 9.

Accordingly, what is involved in this case is essentially statutory double patenting under 35 U.S.C. § 101, as opposed to "obviousness-type" double patenting involved in Heinle and Eli Lilly. Since Heinle and Eli Lilly (1) do not seem to involve statutory double patenting, and (2) statements therein with respect to disclaimers appear to be dictum, neither is controlling authority. To the extent the dictum can be argued to be binding and that there may be a conflict between Heinle and Eli Lilly panel decision. South
Corp. v. United States, 690 F.2d 1368, 215 USPQ 657 (Fed. Cir. 1982) (CCPA and Court of Claims decisions are binding precedent in Federal Circuit until overruled en banc).

The facts of the case bring it within the policy set out in § 804.02 of the MPEP. Notwithstanding the lack of any legal analysis in the MPEP in support of the policy, we have not been given a sufficiently cogent reason for not following the policy. Accordingly, we adopt as the law for this case the policy set out in § 804.02 of the MPEP.8

⁸ We will make the following observation. At the time the policy set out in § 804.02 was adopted, maintenance fees were not required by Congress. We have not overlooked the possibility that through what we will call shenanigans involving filing of disclaimers of patents and terminal disclaimers in applications, an inventor might be able to avoid paying the full maintenance fees required by law to maintain a patent in

In the event a party seeks judicial review of our decision on Tsuruta's preliminary Motion 5, the parties should notify the General Counsel of the USPTO so that the Director can determine whether it would be appropriate to intervene or participate as an <u>amicus</u> for the purpose of defending the policy set out in § 804.02 of the MPEP.

In view of the foregoing, Tsuruta's preliminary Motion No. 5 is <u>denied</u>.

Tsuruta's Preliminary Motion No. 6

In preliminary Motion No. 6, Tsuruta requests judgment that certain of Nardella claims are not patentable to Nardella. Tsuruta argues that since Nardella claims 38 through 42 are not patentable to Nardella, as is argued in Tsuruta's Motion No. 5 above, Nardella's claims 35 through 36 are likewise unpatentable because these claims cover the same

having the same claims as the disclaimed patent, all after an invention becomes

force for 20 years. Thus, it is possible for a patentee (1) to disclaim a patent before the first maintenance fee is due, (2) keep a continuation pending before the USPTO and (3) issue the continuation as a second patent (which would have a shorter patent life)

commercially significant. The patentee could end up paying the cheaper first and second maintenance fees instead of all three maintenance fees required by law. Whether our maintenance fee observation might cause the USPTO to re-think the § 804.02 policy is not an issue before us. We will note that, in this case, Nardella did not disclaim all 29 claims in its patent, just claims 1-3, 5 and 9. Hence, if Nardella wants to keep its patent viable for the entire term authorized by law, it will have to pay all maintenance fees required by law.

invention as claims 38 through 42. This motion is <u>denied</u> for that same reasons stated above for Tsuruta's Motion No. 5.

Preliminary Statements

The preliminary statements are now open on the record and are attached to this paper.

Nardella has been accorded the benefit of several applications including Serial Number 07/786,572 filed November 1, 1991. Tsuruta states in its preliminary statement that it intends to rely on the filing dates of earlier filed Japanese applications, i.e. 4-126246 and 4-126248 filed on May 19, 1992; 4-142930 filed June 3, 1992; 4-144302 and 4-144625 filed June 4, 1992; and 5-72553 filed March 30, 1993. However, Tsuruta was not accorded the benefit of these applications in the declaration of this interference nor has Tsuruta filed a preliminary motion to be accorded the benefit of the filing date of these applications. The filing date of the Tsuruta patent is May 14, 1993.

<u>Judgment</u>

Because Nardella has been accorded the benefit of an application which has a filing date prior the filing date of Tsuruta's involved patent, judgment is herein entered against Tsuruta. Accordingly, Tsuruta is not entitled to a patent with claims 1 and 3. Judgment is herein awarded to Nardella, which on this record is entitled to a patent with claims 35 through 42

which correspond to the Counts 1 or 2.

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Fred E. McKelvey, Senior
Administrative Patent Judge
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Nurriel E. Crawford

PATENT

Administrative Patent Judge
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APPEALS AND
INTERFERENCES
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